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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/612,515

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Kevin T. Stone

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EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/612,515

Applicant(s)

STONE ET AL.

Examiner

Melanie Tyson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 19-42 is/are pending in the application.
- 4a) Of the above claim(s) 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 19-24 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/21/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to applicant's amendments received on 21 December 2006.

Corrections made to the drawings and claims are accepted.

Response to Election Requirement Arguments

1. Applicant's arguments regarding the election requirement filed 21 December 2006 have been fully considered but they are not persuasive. Although applicant points out the bone engaging portion and suture engaging portion in Figure 1, applicant has still failed to show *a suture protection portion on the bone engaging portion* in Species I. This limitation is found on page 27 of the specification (paragraph 82), in which applicant refers to Figures 20-21 (see paragraph 81), or Species II (refer to previous office action). Therefore, claim 25 reads on Species II. Since claims 26-35 depend on claim 25, they also read on Species II. Accordingly, the requirement is still deemed proper and is therefore made FINAL.

Specification

2. The specification is objected to because of the following informalities: a typographical error on page 3 of the amendment. Replace "1346" with --134b--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-5, 9, and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebner (Patent No. 5,868,789). Huebner discloses a suture anchor (Figures 1 and 6) comprising a single unit (14; surgical steel or a bio-absorbable compound, column 4, lines 25-27) having a bone engaging section (32) formed along an axis (dotted line), a bone engaging structure (thread 36) defining a maximum diameter (column 5, lines 2-4), a suture engaging section (46) spaced axially from the bone engaging section (32) and positioned within a boundary defined by the bone engaging section (outside the threaded portion), an eyelet (50; Figure 6 shows a selected portion of a suture passes through and extends generally along the axis), and a suture passage (portion through eyelet 50) substantially only through the suture engaging section (46). Figure 6 further shows the suture engaging section (46) is able to be substantially disposed below an exterior surface of a bony structure (114) after implantation.

5. Claims 19, 20, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Martello (Patent No. 6,168,598 B1). Martello discloses a suture anchor (Figure 1) comprising single material (column 2, lines 1-9) having an anatomical engaging section (threaded portion of shank 17) having an anatomical engaging portion (thread 18), a suture engaging portion (unthreaded portion of shank 17 and up) adapted to be substantially received with the selected anatomical portion (14; unthreaded portion of shank 17), a first suture eyelet (34), a second suture eyelet (32), and a suture holding passage (36).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 6, 7, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner in view of Martello. Huebner discloses a device as described above, however, fails to disclose the eyelet is substantially exposed and accessible after implantation of the suture anchor. Martello discloses a suture anchor (Figure 1) comprising a first eyelet (34) defined by an opening on a proximal face of a suture engaging section (unthreaded portion of shank 17 and up, which has a horizontal axis and a vertical axis), a second eyelet (32), and a passage (36) interconnecting the first eyelet (34) and the second eyelet (32). Figure 4B shows an embodiment in which the passage (52) interconnecting a first eyelet (52u) and a second eyelet (52L) is substantially parallel with the bone-engaging axis (58). Martello teaches the eyelet on the proximal face of the suture-engaging surface is exposed and accessible after

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implantation of the suture anchor (column 2, lines 11-15; see Figure 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made in order to place the eyelet of Huebner on a proximal face of the suture engaging section as taught by Martello such that the eyelet is exposed and accessible after implantation of the suture anchor in order to facilitate the procedure by eliminating the need for a multiplicity of specialized tools to attach sutures (column 2, lines 12-22).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebner in view of Martello as applied to the claims above, and further in view of Borzone et al. (Patent No. 5,814,070). Huebner in view of Martello discloses a device as described above, however, fails to disclose that the suture passage allows a suture to be passed to an exterior of the suture engaging portion at a point other than the first and second eyelets. Borzone et al. disclose a suture anchor (Figure 6) comprising a suture engaging section (36) and a bone engaging section (34). Borzone teaches a suture passage (38) that allows a suture to be passed exterior of the suture engaging section (column 4, lines 3-18). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the suture passage of Huebner in view of Martello as taught by Borzone et al. in order to distribute the stress on the suture material over the diameter of the distal end (column 4, lines 11-13), thus minimizing the risk of breakage of the suture material.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martello. In addition to the device described above, Martello teaches alternate embodiments in which the passages can be of different angles with respect to the anatomical engaging

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axis. For example, Figure 4B shows the passage (52) that interconnects the first eyelet (52u) and second eyelet (52L) is substantially parallel with the bone-engaging axis (58) such that a suture is generally able to extend generally parallel along an axis (58) of the anatomical engaging section. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a passage that allows a suture to extend generally parallel along an axis of the anatomical engaging section as taught by Martello in order to facilitate a procedure that would require this particular angle of tissue attachment (column 1, lines 32-34).

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martello in view of Borzone et al. Martello discloses a device as described above, however, fails to disclose the passage includes a first passage section and a second passage section formed at an angle relative to each other to have an angle of at least 90 degrees.

Borzone et al. disclose a suture anchor (Figure 2) comprising a suture engaging section (16) and an anatomical engaging section (threaded portion). Borzone et al. teach the suture holding passage (20) includes a first passage and a second passage section formed at an angle relative to each other to have an exterior angle of at least 90 degrees (U-shaped; column 3, lines 21-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the passage of Martello as taught by Borzone et al. in order to maximize the area of stress of the suture material along the U-shaped passage (20), thus minimizing the risk of breakage of the suture material (column 3, lines 30-37).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
March 1, 2007

MT


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

2/5/07